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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/247,406	02/10/99	CAPLAN M	HS105

EXAMINER	
WESSENDORF, T	
ART UNIT	**PAPER NUMBER**
1627	9

HM12/0226

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DATE MAILED: 02/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/247,406	Caplan
Examiner	**Group Art Unit**
T. Wessendorf	1627

☒ Responsive to communication(s) filed on 12/1/00

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-3, 5-17, 19-23, and 46-53 is/are pending in the applicat

. Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5-17, 19-23, and 46-53 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 21-22, 46-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recited "..first polypeptide, while retaining at least one desirable characteristic of the first polypeptide"; "wherein either or both the antibody reactivity and the alteration in the antibody reactivity are associated with an undesirable immune response" are not supported in the as-filed specification. It is requested that applicants point out specifically where in the specification the present claim limitations appear.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-17, 19-23 and 46-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 1 is confusing. The preamble recites a method to identify a mutant polypeptides while the body of the claim recites for screening for retention of the desirable characteristic. It is not clear, within the claimed context, in what aspects the first polypeptide is advantageous. Also, is the advantageous characteristic different or the same from the desirable characteristic? The use of different terms to mean the same thing provides for confusion and ambiguity. What is the maximum characteristics or the kind that are retained by the mutant polypeptide? Furthermore, it is not clear, within the claimed context, the aspect or basis by which a polypeptide is considered a 'first' polypeptide. Is the first polypeptide, the parent or an altered form of a polypeptide? Also, as stated in

the last Office action, the recited "monospecific" within the claimed context, as used in the alternative reaction with an antibody and fragments of antibodies is indefinite. Also, it is not clear within the claimed context, the difference between the antibody being associated or involved in the undesirable immune response, especially in the absence of positive showing in the specification. (See the last Office action, for which no response to these rejections have been provided).

B). Claim 22 is confusing. The preamble recites for altering an antibody mediated or associated reaction in an individual but the body does not recite an alteration that is mediated (i.e., caused)by an antibody rather, what appears to be mediated by the (antigenic?)polypeptide. Furthermore, it is not clear how the polypeptide is considered to have an altered antibody reactivity. The process steps recited in the body of the claim appear not to correspond with one another or with the preamble or the intended use of the method claimed. "The" amino acid sequence lacks antecedent basis from the preceding statement. This claim appears to be a duplicate of claim 1. Both claims recite the same process steps except differing in the language of the preamble.

C). Claim 21 recitation of "the polypeptide of interest" lacks antecedent basis of support and inconsistent with the "first polypeptide". This rejection also applies to claim 46.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5-8, 9, 11-14, 16-17, 19, 21, 46-49 and 52-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Hakkart et al (Allergy) for reasons of record.

Applicants admit that Hakkart has observed that the polypeptides still bound IgE and therefore release histamine. But argue that there was no screening for an advantageous property such as inducing IgG production, which could be used to induce tolerance in an allergic patient. Applicants argument is not commensurate in scope with the claims. The claims do not recite the argued advantageous property of inducing IgG production. [Note claim 8 recites reactivity not only to IgG but also to IgE.] Furthermore, the claims recite for identifying for a mutant polypeptide and not for its advantageous property. It is

considered that this advantageous property is inherent to the method of Hakkart.

Claims 1-3, 8, 9, 11-14, 16-17, 19, 21-23, 46-49 and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated Smith (J. Allergy and Clin. Immuno.)for reasons advanced in the last Office action.

The arguments over Hakkart above are applied herein since applicants merely present the same arguments, as above.

Claims 1-3, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Jespers et al (The. Jrnl, Mol. Biol.) for reasons of record.

It is argued that Jespers is similar to e.g., Smith except that the protein is not an allergen. These claims do not recite the protein as an allergen rather, any type of mutant polypeptide.

Claims 6, 7 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakkart et al in view of Steinberger et al (The Jrnl. of Biol.Chemistry) for reasons advanced in the also Office action.

See the arguments above under Hakkart since applicants argue that Steinberger, like Hakkart, does not screen for the ability to elicit IgG production.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hakkart et al in view of Espanion (DTW).

Applicants argue that since Hakkart does not make obvious the claimed method hence, the combination does not make the method obvious. The reasons presented under Hakkart is applied herein. For the reasons set forth by Espanion as to the potential applications of gene transfer in farm animals for increased disease resistance and transgenic animal could be an attractive alternative for conventional production methods, one having ordinary skill in the art would be motivated to use transgenic animals or plant methods.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is

not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993)(see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T. Wessendorf
Patent Examiner
Art Unit 1627
2/26/01